or work on materials that HCFA concludes is necessary to determine the laboratory's continued eligibility for its CLIA certificate or continued compliance with performance standards set by HCFA;

(5) Refused a reasonable request by HCFA or its agent for permission to inspect the laboratory and its operation and pertinent records during the hours that the laboratory is in operation;

(6) Violated or aided and abetted in the violation of any provisions of CLIA and its implementing regulations;

(7) Failed to comply with an alternative sanction imposed under this subpart; or

(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked. (This provision applies only to the owner or operator, not to all of the laboratory's employees.)

(b) *Adverse action based on improper referrals in proficiency testing.* If HCFA determines that a laboratory has intentionally referred its proficiency testing samples to another laboratory for analysis, HCFA revokes the laboratory's CLIA certificate for at least one year, and may also impose a civil money penalty.

(c) *Adverse action based on exclusion from Medicare.* If the OIG excludes a laboratory from participation in Medicare, HCFA suspends the laboratory's CLIA certificate for the period during which the laboratory is excluded.

(d) *Procedures for suspension or limitation*—(1) *Basic rule.* Except as provided in paragraph (d)(2) of this section, HCFA does not suspend or limit a CLIA certificate until after an ALJ hearing decision (as provided in §493.1844) that upholds suspension or limitation.

(2) *Exceptions.* HCFA may suspend or limit a CLIA certificate before the ALJ hearing in any of the following circumstances:

(i) The laboratory's deficiencies pose immediate jeopardy.

(ii) The laboratory has refused a reasonable request for information or work on materials.

(iii) The laboratory has refused permission for HCFA or a HCFA agent to inspect the laboratory or its operation.

(e) *Procedures for revocation.* (1) HCFA does not revoke any type of CLIA certificate until after an ALJ hearing that upholds revocation.

(2) HCFA may revoke a CLIA certificate after the hearing decision even if it had not previously suspended or limited that certificate.

(f) *Notice to the OIG.* HCFA notifies the OIG of any violations under paragraphs (a)(1), (a)(2), (a)(6), and (b) of this section within 30 days of the determination of the violation.

§493.1842 Cancellation of Medicare approval.

(a) *Basis for cancellation.* (1) HCFA always cancels a laboratory's approval to receive Medicare payment for its services if HCFA suspends or revokes the laboratory's CLIA certificate.

(2) HCFA may cancel the laboratory's approval under any of the following circumstances:

(i) The laboratory is out of compliance with a condition level requirement.

(ii) The laboratory fails to submit a plan of correction satisfactory to HCFA.

(iii) The laboratory fails to correct all its deficiencies within the time frames specified in the plan of correction.

(b) *Notice and opportunity to respond.* Before canceling a laboratory's approval to receive Medicare payment for its services, HCFA gives the laboratory—

(1) Written notice of the rationale for, effective date, and effect of, cancellation;

(2) Opportunity to submit written evidence or other information against cancellation of the laboratory's approval.

This sanction may be imposed before the hearing that may be requested by a laboratory, in accordance with the appeals procedures set forth in §493.1844.

(c) *Effect of cancellation.* Cancellation of Medicare approval terminates any Medicare payment sanctions regardless of the time frames originally specified.

§493.1844 Appeals procedures.

(a) *General rules.* (1) The provisions of this section apply to all laboratories and prospective laboratories that are